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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,380	09/29/2000	Andre T. Baron	99-057	1919

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12/21/2005

EXAMINER
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BORGEEST, CHRISTINA M

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/676,380	BARON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-23 is/are allowed.
- 6) ☒ Claim(s) 9-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicants' amendment received 13 September 2004 is acknowledged. Claims 9 and 18 have been amended. Claims 1-23 are pending. Claims 1-8 remain withdrawn from consideration as being directed to a non-elected invention. Claims 9-23 are currently pending and under examination. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action mailed 14 January 2003.

### ***Claim Rejections Withdrawn***

The rejection of claims 9-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in response to Applicants' amendment of claim 18.

### ***Claim Rejections Maintained***

#### ***Claim Rejections - 35 USC § 103***

Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harvey et al., U.S patent 5,674,753, 1997, Partanen et al. (J. Occup. Med., 1994, vol. 36, pp 1324-1328) or Witters et al. (Clin. Cancer Res., 1995, vol. 1, pp.551-557) in view of Graus-Porta et al. (EMBO J., 1997, vol. 16, pp. 1647-1655) or Olayioye et al. (J. Biol.

Chem., 1999, vol. 274, pp. 17209-17218), and further in view of WO 94/1 1734 (Johansen et al., 1994) is maintained for reasons of record in the office actions mailed 7 May 2002, 14 January 2003 and 29 July 2003. Applicants state that prior comments show that the inventions cited by the examiner do not teach the present invention, their combination does not result in Applicants' invention, and they do not make Applicants' invention obvious and that the prior citation of Baron et al. was to show the limitations of that prior art. Applicants' arguments have been fully considered but they are not persuasive. As outlined in the prior office actions dated 14 January 2003 and 29 July 2003 the antibodies used by Applicant were known in the art and no experimentation was required to develop them. There is nothing in the instant claims that requires an improvement in ability or sensitivity over the assays taught in the prior art. Baron et al. (J. Immunol. Meth. 1998, vol. 219, pp. 23-43—cited by Applicants in correspondence received 14 May 2003) does not provide evidence that the method developed by Applicant is superior because the comparison is not to that which the examiner has cited as the prior art, and because, according to Applicants' arguments, the assay of Baron is not the claimed assay. Thus the rejection of claims 9-17 under U.S.C. 103 is maintained.

***Allowable Subject Matter***

In view of Applicants' amendment to claim 18 to placing it in independent form, this places claims 18-23 in condition for allowance.

***Conclusion***

Claims 9-17 are rejected. Claims 18-23 contain allowable subject matter.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1649

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christina Borgeest, Ph.D.  
December 8, 2005

*Elizabeth C. Kemmerer*

**ELIZABETH KEMMERER  
PRIMARY EXAMINER**